

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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BIOFER S.P.A.,

Plaintiff,

-against-

ORDER

22-CV-2180-AMD-SJB

VIFOR (INTERNATIONAL) AG.,

Defendant.

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BULSARA, United States Magistrate Judge:

In this patent infringement action, Plaintiff Biofer S.p.A (“Biofer”) alleges Defendant Vifor (International) AG. (“Vifor”) infringed U.S. Patent No. 8,759,320 (the “’320 Patent”), which describes a process used in the creation of iron replacement therapy medicines. (Compl. dated Apr. 15, 2022 (“Compl.”), Dkt. No. 1 ¶¶ 4–10). The invention claimed in the ’320 Patent is the “process for the preparation of trivalent iron complexes with mono-, di- and polysaccharide sugars.” (’320 Patent at [54]).

The parties agree on the construction of all but two claim terms: (1) “pH between 7.0 and 9.0,” and (2) “said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups.” (Joint Disputed Claim Terms Chart, Dkt. No. 44 at 1). The Court conducted a *Markman* hearing on August 3, 2023. The Court concludes that the term “pH between 7.0 and 9.0” should be construed as “pH is maintained in the interval separating 7.0 and 9.0,” while the term “said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups” be construed as “said hypochlorite being added in a 1:1 molar ratio with respect to the aldehyde end groups, with the exception of a 2:1 molar ratio with respect to dextran.”

DISCUSSION

To be valid, “a patent must describe the exact scope of an invention and its manufacture to ‘secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.’” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (alterations in original) (quoting *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891)). To this end, patents must include both a “specification describing the invention ‘in such full, clear, concise terms as to enable any person skilled in the art . . . to make and use the same’” and “‘claims,’ which ‘particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention.’” *Id.* (alterations in original) (quoting 35 U.S.C. § 112). The claim “defines the scope of the patentee’s rights.” *Id.* at 372. And the scope of such a claim, or “the construction of a patent, including terms of art within its claim,” is “‘exclusively’ for ‘the court’ to determine.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) (quoting *Markman*, 517 U.S. at 372).

To “determin[e] the proper construction of a claim, ‘the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and if in evidence, the prosecution history.’” *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1152 (Fed. Cir. 1997) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Such “intrinsic evidence” is “the most significant source of the legally operative meaning of the claim language.” *Id.* (quoting *Vitronics Corp.*, 90 F.3d at 1582). “[T]he words of a claim are generally given their ordinary and customary meaning.” *Easyweb Innovations, LLC v. Twitter, Inc.*, No. 11-CV-4550, 2016 WL 1253674, at *5 (E.D.N.Y. Mar. 30, 2016) (Bianco, J.) (quotations omitted) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)), *aff’d*,

689 F. App'x 969, 971 (Fed. Cir. 2017). This “ordinary and customary meaning” is determined with reference to how “a person of ordinary skill in the art in question . . . as of the effective filing date of the patent application” would understand them “in the context of the entire patent.” *Id.* (quoting *Phillips*, 415 F.3d at 1313). Next, only if ambiguity remains, a court may look to extrinsic evidence—for example, expert testimony. *CVI/Beta Ventures, Inc.*, 112 F.3d at 1152–53.

Vifor makes the active ingredient for an injectable iron sugar product (Injectafer), and has patented this process for making such sugars. On June 24, 2014, the '320 patent, titled “Process for the Preparation of Trivalent Iron Complexes with Mono-, Di- and Polysaccharide Sugars,” was issued to inventors Stefania Sacchi, Mauro Montorsi, and Egidio Marchi. ('320 Patent at [54], [75]). Biofer was the assignee on the patent. (*Id.* at [73]). Biofer alleges that Vifor's process for making iron sugars infringes on the '320 Patent.

The '320 Patent describes a multi-step process for making trivalent iron (III) complexes with sugars. (*Id.* at col. 1, ll. 6–7). The resulting iron complexes are used in therapies to prevent and treat iron deficiency. (*Id.* at col. 1, ll. 12–18). Though the creation of trivalent iron complexes with sugars is not itself novel, (*id.* at col. 1, ll. 19–23), the invention aims to produce complexes with “good physical-chemical stability over time, low toxicity, use safety also by injection and a good bioavailability.” (*Id.* at col. 8, ll. 54–59).

The '320 patented process consists of four steps: (1) the activation of a sugar; (2) “complexation of the activated sugar with ferric hydroxide generated in solution;” (3) “purification of the [resulting] ferric hydroxide/sugar complex still not stabilized;” and (4) “stabilization of the [resulting] complex.” ('320 Patent at col. 8, ll. 62–66).

Both disputed claim terms arise from the first step—the creation of an “activated sugar” through oxidation—and are recited in claim 1 of the patent. (*Id.* at col. 16, ll. 44–56). This step is, in essence, a reaction whereby the end aldehyde group—a group of compounds made up of carbon atoms sharing a double bond with an oxygen atom, and sharing a single bond with another atom, found at the end of a chain of sugar molecules—is transformed into carboxylic acid through a loss of electrons. (Decl. of Jeffrey D. Winkler in Supp. of Pet. for Inter Partes Review (“Winkler IPR Decl.”), Dkt. No. 46-3 ¶¶ 27–28). Claim 1, in relevant part, states:

1. A process for the preparation of an activated sugar comprising the step of reacting a sugar having an aldehyde end group with bromine in a solution at a *pH between 7.0 and 9.0* with the specific oxidation of the end aldehyde, wherein
 - i) said sugar is selected from the group consisting of dextrans and dextrans and wherein
 - ii) said bromine is produced in situ through the addition of a hypochlorite and an alkaline or earth alkaline metal bromide to said solution, *said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups*, wherein said hypochlorite is added instant by instant, such that an excess of hypochlorite in solution is never present.

(’320 Patent at col. 16, ll. 44–56 (emphasis added)). In this case, the oxidation is performed by using the element bromine, which is to be produced “in situ,” *i.e.*, creating bromine by adding sodium hypochlorite (commonly known as chlorine bleach) to a solution of the sugar and water. (Winkler IPR Decl. ¶ 28). But the parties dispute how the ’320 Patent claims this step is performed to create the necessary result: (1) whether the pH range is 7.0–9.0 or includes an error range, and whether the solution must be “maintained” between 7.0 and 9.0 or includes any process in which, at any point, the pH dips into that range, however briefly; and (2) whether when the hypochlorite is added in “stoichiometric quantities,” it is added in a ratio of 1 mole of hypochlorite for every 1

mole of the end aldehyde, or can be added in “approximately” a 1:1 ratio, with the caveat that in the specific case of the dextran, hypochlorite would be added in an approximately 2:1 molar ratio. (Joint Disputed Claims Chart dated May 12, 2023, Dkt. No. 44; Tr. dated Aug. 3, 2023 (“Markman Tr.”), Dkt. No. 82 at 98:4–25).

I. “pH between 7.0 and 9.0”

For the first claim term—“pH between 7.0 and 9.0”—the parties’ dispute is two-fold: whether the term includes an error range and whether the claim only protects a reaction where the pH is “maintained” in this interval during the described process. Biofer contends that the claim should be construed to mean “pH range of between 6.8 and 9.2,” (Pl. Biofer’s Opening Claim Construction Br. dated June 12, 2023 (“Biofer Op. Br.”), Dkt. No. 45 at 21), while Vifor asserts it should be construed as: “pH is maintained in the interval separating 7.0 and 9.0.” (Def. Vifor’s Responsive Claim Construction Br. dated July 12, 2023 (“Vifor Resp. Br.”), Dkt No. 62 at 11). The Court adopts Vifor’s proposed construction.

i. “7.0 and 9.0”

The Court first addresses whether “pH between 7.0 and 9.0” means “pH between 6.8 and 7.2.” It does not. Precise claim terms without qualifying language—such as about, around, or approximately—mean what they say; that is, these precise values are to be taken as the plain meaning, absent evidence to the contrary. *See, e.g., Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1381 (Fed. Cir. 2000) (“Without broadening words that ordinarily receive some leeway, the precise weight ranges of claim 1 do not ‘avoid a strict numerical boundary to the specified parameter.’” (alteration, citation, and quotations omitted)); *Cobalt Boats, LLC v. Brunswick Corp.*, 773 Fed. App’x 611, 616 (Fed. Cir. 2019) (“Where a precise value is included in the claim

without a term such as ‘about,’ we interpret the claim language as imposing a strict numerical boundary, absent evidence that such a construction would be inconsistent with the intrinsic evidence.”). Here, the claim language contains precise values without qualifying language. Rather than claiming a pH “about, around, or approximately between 7.0 and 9.0” or “ 7.0 ± 0.2 and 9.0 ± 0.2 ,” the inventors claimed a precise pH range: between 7.0 and 9.0. (’320 Patent at col. 16, l. 46).

“Assigning [such] numerical precision to . . . ranges [] is particularly appropriate when other variables in the same claims explicitly use qualifying language.”

Jeneric/Pentron, Inc., 205 F.3d at 1381. The patent here contains several examples of qualifying language in the claimed invention and in the specifications. For instance, claim 5 states, “the hypochlorite added is in an aqueous solution containing *about* 12% by weight of active chlorine.” (’320 Patent, col. 16, ll. 65–67 (emphasis added)). And, the patent’s specifications for reactions other than oxidation use language and symbols indicating approximation, including “about” and “ \pm .” (*E.g.*, *id.* at col. 11, ll. 31–32 (“pH is brought to 11.0 ± 0.5 ”); *id.* at col. 12, l. 22 (same); *id.* at col. 11, l. 45 (“pH of 10.5 ± 5 ”); *id.* at col. 12, l. 34 (same); *id.* at col. 13, l. 7 (“pH of 10.5 ± 0.5 ”); *id.* at col. 13, l. 52 (same); *id.* at col. 13, l. 14 (“ 11.5 ± 0.5 ”); *id.* at col. 11, l. 38 (“ $85 \pm 2^\circ \text{C.}$ ”); *id.* at col. 11, l. 47 (“ $90 \pm 2^\circ \text{C.}$ ”), *id.* at col. 13, ll. 14–15 (“ $75^\circ \text{C.} \pm 2$ ”)). But such qualification is absent with respect to the pH range in this claim.

The prosecution history also supports a precise reading and runs contrary to Biofer’s interpretation. “The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Actelion Pharms. Ltd. v. Mylan*

Pharms. Inc., 85 F.4th 1167, 1173 (Fed. Cir. 2023) (quotations omitted). A court “must . . . examine the prosecution history to determine whether the patentee has relinquished a potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference.” *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001).

In one of its amendments, Biofer claimed “[a] process for the preparation of an activated sugar comprising the step of reacting a sugar having an aldehyde end group with bromine in a solution at a pH between 7 and 9 . . .,” i.e., without the decimal and zero digit. (Patent Amendment A filed Sept. 13, 2007, attached as Ex. 8 to Decl. of Sanya Sukduang in Supp. of Vifor’s Responsive Claim Construction Br. (“Sukduang Decl.”), Dkt. No. 63-8 at 3 (emphasis added)). The Examiner rejected that claim because prior art covered claims “at a pH of about 9.” (U.S. Patent and Trademark Office Action dated Nov. 17, 2011, attached as Ex. 9 to Sukduang Decl., Dkt No. 63-9 at 4). In response, Biofer amended and sought the current claim language, “pH between 7.0 and 9.0,” arguing that “the invention as now claimed . . . involves an inventive step over the prior art.” (Patent Amendment C dated Feb. 26, 2013, attached as Ex. 11 to Sukduang Decl., Dkt No. 68-10 at 8). Biofer’s use of precision to overcome prior art, which defined the upper pH bound with the qualifier “about,” is further evidence that the current claim language is precise, not an approximation. *See, e.g., MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1311–12 (Fed. Cir. 2017) (finding statements from the prosecution of a related parent patent used to overcome prior art were relevant to defining the scope of the invention).

Biofer nonetheless contends that the pH values “were expressly defined by the patentee/inventor during prosecution to have an error range of ± 0.2 .” (Biofer Op. Br. at

21). Specifically, Dr. Myerson, one of Biofer’s experts, declared that “a POSA¹ would understand the meaning and scope of the disputed claim language as encompassing a pH range from 6.8 to 9.2” because of the way Dr. Marchi, an inventor, performed experiments replicating the examples in the patent. (Decl. of Allan S. Myerson, Ph.D. in Supp. of Pl. Biofer’s Op. Claim Construction Br. dated June 12, 2023 (“Myerson Decl.”), Dkt. No. 48 ¶ 35). Dr. Marchi’s declaration (“the Marchi Declaration”) details several experiments he supervised, replicating examples from the ’320 Patent. (Decl. of Egidio Marchi dated June 13, 2013 (“Marchi Decl.”), attached as Ex. 12 to Sukduang Decl., Dkt. No. 63-12 at 18–26). In the Marchi Declaration, Dr. Marchi explains an experiment replicating Example 5 “at a pH of 8.0.” (*Id.* ¶ 3). It states that “the pH is adjusted to a value of 8.0” and the “[s]odium hypochlorite . . . is slowly added over 2h maintaining the pH between 7.8 and 8.2.” (*Id.*). He then explains Experiment 2, which replicated Example 5 “at a pH of 10.0.” (*Id.* ¶ 4). It states, “the pH is adjusted to a value of 10.0” and “[s]odium hypochlorite . . . is slowly added over 2h maintaining the pH between 9.8 and 10.2.” (*Id.*).

These experiments, Biofer suggests, means that the claimed pH values should be given an error range of ± 0.2 . The argument reads too much into the sounds of silence. The Marchi Declaration never states that he understood the claimed pH range to include an error range, of ± 0.2 or otherwise. As for the experiments, one of them, Experiment 2, takes place entirely outside of the claimed range of 7.0 and 9.0 (between 9.8 and

¹ A POSA is a “person of ordinary skill in the art in question at the time of the invention.” *Phillips*, 415 F.3d at 1313. “The terms used in patent claims are not constructed in the abstract, but in the context in which the term was presented and used by the patentee, as it would have been understood by a person of ordinary skill in the field of the invention on reading the patent documents.” *Fenner Invs., Ltd. v. Cellico P’ship*, 778 F.3d 1320, 1322–23 (Fed. Cir. 2015).

10.2), providing little or no insight into the question here. (*See* Marchi Decl. ¶ 4). The other never goes to the range that Biofer seeks. That is, Experiment 1 never dips down to a pH of 6.8 or rises to 9.2 and reflects only that it was conducted between 7.8 and 8.2, not at the outer bounds of the claimed invention. (*Id.* ¶ 3). Again, this experiment provides no insight into the tolerance available for the outer bounds of the claim, which is the issue here. Ultimately, however, there is no reason to mine the Marchi Declaration for its unstated implications because the claimed invention language, as noted above, is clear. *See Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319 (Fed. Cir. 2006) (“Where, as here, the written description clearly identifies what his invention is, an expression by a patentee during prosecution that he intends his claims to cover more than what his specification discloses is entitled to little weight.”). And that clear language contains no error range or qualification or other reference suggesting that a “pH between 7.0 and 9.0” should mean “between 6.8 and 7.2.” Had the inventors intended the claim to mean “6.8 and 9.2,” they could have easily done so. But they did not.

ii. “Between”

As noted, the invention claimed is “[a] process for the preparation of an activated sugar comprising the step of reacting a sugar having an aldehyde end group with bromine in a solution at a pH between 7.0 and 9.0 with the specific oxidation of the end aldehyde.” (’320 Patent at col. 16, ll. 44–47). The parties disagree as to whether the term “pH between 7.0 and 9.0” means “a pH maintained in the interval separating 7.0 and 9.0.” That is, they disagree whether the claim encompasses only a process which occurs *entirely* at a pH between 7.0 and 9.0, or if the claim covers a process where the

pH falls within that range at any time, even briefly.² The Court concludes that the term means “a pH maintained in the interval separating 7.0 and 9.0.”

After looking at the words of the claims themselves, “it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning.” *Vitronics Corp.*, 90 F.3d at 1582. “The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” *Id.* This Court “must interpret the claims in light of the specification yet avoid impermissibly importing limitations from the specification.” *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) (citation omitted). But “[i]t is . . . entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims.” *Phillips*, 415 F.3d at 1317. That is, “the written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed.” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001). In fact, not only is the specification highly relevant to the analysis, “[u]sually, it is dispositive,” and serves as “the single best guide to the meaning of a disputed term.” *Vitronics Corp.*, 90 F.3d at 1582. Accordingly, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

² Both sides contend that their construction encompasses the “plain and ordinary meaning” of the word “between.” (See Vifor Resp. Br. at 12; Pl. Biofer’s Reply Claim Construction Br. dated July 19, 2023 (“Biofer Reply Br.”), Dkt. No. 67 at 3–5).

The intrinsic evidence supports Vifor’s construction.³ In the Description of the Invention, the ’320 Patent states that if “an excess of hypochlorite [is] present . . . oxidation secondary reactions could occur.” (’320 Patent, col. 7, ll. 14–17).⁴ As such, it goes on to warn: “it is important to *maintain the reaction pH* in the range between 5.0 and 12.0, preferably, between 7.0 and 9.0, since in this pH range the bromine consumption takes place at a high rate leading to the oxidation of the aldehyde end group.” (*Id.* at col. 7, ll. 18–22 (emphasis added)). And in the Detailed Description of the Invention, the patent states: “Throughout the activation reaction of the sugar, the pH value is *controlled and maintained in the fixed range*, preferably between 7.0 and 9.0[.]” (*Id.* at col. 9, ll. 24–26 (emphasis added)).

Where “a patent ‘repeatedly and consistently’ characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization.” *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370 (Fed. Cir. 2016). Biofer’s assertion that the term “maintain” is used only occasionally and only in the specification, (Biofer Op. Br. at 24), not only downplays the importance of the specification, *supra* at 10, but also the pervasive use of the term. The reference is more than occasional, and *each* example which mentions the pH between 7.0 and 9.0 instructs that the pH is to be maintained during oxidation. (’320 Patent at col. 11, ll. 13–

³ “Intrinsic evidence includes the patent’s claims, specification, and prosecution history.” *Grace Instrument Indus., LLC v. Chandler Instruments Co.*, 57 F.4th 1001, 1008 (Fed. Cir. 2023); *see also supra* at 2–3.

⁴ If an excess of hypochlorite is present “in addition to bromine in the reaction environment, oxidation secondary reactions could occur, which would relate to other parts of the end sugar and to depolymerization phenomena.” (’320 Patent at col. 7, ll. 15–18). “[D]epolymerization, if it’s excessive, can be problematic or undesirable.” (Markman Tr. at 9:14–15).

14 (Example 1) (“maintaining the pH value between 7.0 and 9.0”); *id.* at col. 12, ll. 59 (Example 3) (same); *id.* at col. 13, ll. 35–38 (Example 4) (same); *id.* at col. 14, ll. 13–16 (Example 5) (“The pH of the solution is brought to a value between 7.0 and 9.0 with a sodium hydroxide solution and over 2 hours, 48.66 g of 12% w/v active chlorine sodium hypochlorite are added, maintaining the pH within the fixed limits.”); *id.* at col. 14, ll. 66–67 (Example 6) (“[A]dded over two hours, maintaining the pH value between 7.0 and 9.0.”); *id.* at col. 15, ll. 46–47 (Example 7) (same)). Accordingly, the Court finds that the intrinsic evidence supports that the pH range must be maintained throughout the process. *See, e.g., GPNE Corp.*, 830 F.3d at 1370–71 (finding that a “node” is classified as a “pager,” where the specification “repeatedly and exclusively use[d] [the words “pager” and “pager units”] to refer to the devices in the patented system,” even where “nothing in the claim required that a ‘node’ must be a ‘pager’”); *Wisc. Alumni Rsch. Found. v. Apple Inc.*, 905 F.3d 1341, 1351 (Fed. Cir. 2018) (finding the meaning of “prediction” encompassed only dynamic—not static—predictions where the term was described as dynamic throughout the entire patent and no specifications described the prediction as static, and rejecting Apple’s argument that this construction “improperly imported a limitation from the preferred embodiment”).

Biofer contends that this construction improperly reads the word “maintain” into the claim, and that all the term means is that a sugar is reacted with bromine in a solution at a pH between 7.0 and 9.0. (Biofer Reply Br. at 1). To Biofer, this means there need not be “ongoing pH control for the entirety of the process,” (*id.* at 2), because “[b]etween says nothing about time,” and there is “no restriction intrinsically on duration that you spend within that range,” (Markman Tr. at 26:24–25, 27:4–5). Biofer argues that all “a pH between 7.0 and 9.0” means is that there is a range of pH values

between 7.0 and 9.0, (*id.* at 25:3–4), and there is no reason, at this point, to discuss “duration, time, [or] excursions,” because the claim is “plain on its face.” (*Id.* at 27:6–10).

Essentially, this boils down to Biofer arguing that construing the claim based on the language in the specification (*i.e.*, the experiments) is improper because claims of a patent are not limited to the examples in the specification. (Biofer Op. Br. at 24). Again, this downplays, if not mutes, the central role the specification plays in understanding the meaning of a disputed term. *Supra* at 10. None of the cases cited provides support for the rule or result Biofer seeks. Biofer points to *Ekchian v. Home Depot, Inc.*, in which the Court found that the preferred embodiment did not limit the claim where the party relied *only* on the embodiments to advance its claim interpretation. 104 F.3d 1299, 1303 (Fed. Cir. 1997) (“Lucas identifies nothing further to support its contention that the term ‘conductive’ is limited to the conductivity levels inherent in the disclosed examples. . . . We therefore conclude that the term is not so limited.”). Of course, here, Vifor’s interpretation of “maintain” is based on more than the specification. But *Ekchian* also does not stand for the proposition that the specifications cannot inform the Court of the limitations of the claim; in fact, it follows the general, understood approach: “examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term.” *Id.* It only warns that “the scope of the claim is *not necessarily* limited by such examples.” *Id.* (emphasis added). So, the case offers no comfort to Biofer, which is attempting to define the contested term solely on the basis of undisclosed embodiments.

Biofer also points to *Falana v. Kent State University* to show that the Court should not limit the scope because of the examples. 669 F.3d 1349, 1355 (Fed. Cir.

2012). In *Falana*, the Federal Circuit found that the district court did not err in failing to limit the claims “to an optically active compound ‘having a substantially temperature independent [HTP]’” where “the plain language of the claims nowhere suggests a limitation regarding temperature independent HTP, let alone a temperature [across a specific range].” *Id.* at 1354–55.

This case is not *Falana*: here, the claim language *itself* suggests a limitation. It instructs that “an excess of hypochlorite” should never be present in the solution. (’320 Patent at col. 16, ll. 50–56). The description of the invention merely explains the impact of failing to abide by that limitation. If there is an excess of hypochlorite, combined with bromine in the environment, oxidation secondary reactions could occur. (*Id.* at col. 7, ll. 14–18). To avoid this, it instructs “it is important to *maintain* the reaction pH in the range between 5.0 and 12.0, preferably, between 7.0 and 9.0.” (*Id.* at col. 7, ll. 18–20).

Because all the specifications that mention a pH between 7.0 and 9.0 mention that the pH must be maintained, the Court finds that Biofer’s proposed construction—covering any reaction that dipped into the range, even briefly—would “expand the scope of the claims far beyond any-thing described in the specification.” *Wisc. Alumni Rsch. Found.*, 905 F.3d at 1351–52 (quoting *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1019 (Fed. Cir. 2009)) (finding that constructing the word “prediction” to include dynamic and static predictions where the specifications only illustrated dynamic predictions would improperly broaden the scope of the claim).

For the first time in its reply brief, Biofer argues that Vifor ignores the word “comprising” in the claim, which it argues “indicates that the claim is open-ended and allows for additional steps.” (Biofer Reply Br. at 2 (quoting *Solvay S.A. v. Honeywell Int’l Inc.*, 742 F.3d 998, 1005 (Fed. Cir. 2014))). Biofer claims that “the Federal Circuit

has repeatedly held that such open-ended ‘comprising’ claims involving reaction steps do not require the claimed conditions to be maintained for the entire duration, and permit part of those reactions to occur at unclaimed conditions.” (*Id.*). The Court does not read Biofer’s cited cases as supporting its belated argument.

In *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, the Federal Circuit found that “[t]he transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.” 327 F.3d 1364, 1368 (Fed. Cir. 2003). There, the Court found that when the word “comprising” introduces recited steps—as it does here—that “the claim signals to patent practitioners that [the claim] allows activity . . . *before* the recited steps.” *Id.* (emphasis added). It goes on to say that “activity *outside* the claim, of course, is not limited by the temperature range recited in claim 1.” *Id.* (emphasis added). *Invitrogen* does not support Biofer’s position. Biofer is not arguing that there is an additional step outside of claim 1 that should not be limited by virtue of the limitations in the claim. Instead, Biofer is seeking to expand the claim to permit reactions outside of the pH claimed in claim 1. (Biofer Reply Br. at 1–2). Biofer’s position is that the process *within* the claim should not be limited by the claim language, where *Invitrogen* stands for the proposition that activity *outside* the claim should not be limited by the claim language, and that “claim language and its form do not restrict activities . . . that occur *before* the claimed method.” *Invitrogen*, 327 F.3d at 1368 (emphasis added).⁵

⁵ *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.* likewise stands for the proposition that when a claim uses the term “comprising,” “additional step[s] [are] permissible.” 320 F.3d 1339, 1350 (Fed. Cir. 2003). There, the district court erred in rejecting an additional period of incubation time beyond the required minimum time reflected in the claim, because “the utility of claim 1 is not premised on a

The Court finds that the intrinsic evidence supports Vifor's construction and that Biofer's counterarguments are without merit. Accordingly, the Court adopts Vifor's proposed construction.

II. "Said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups"

The second disputed term reads: "said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups." ('320 Patent at col. 16, ll. 52–54). Vifor argues that to add hypochlorite in "stoichiometric quantities" while ensuring that an "excess of hypochlorite in solution is never present," ('320 Patent at col. 16, ll. 55–56), hypochlorite cannot be added in more than a 1:1 molar ratio with respect to the end aldehyde. (Vifor Resp. Br. at 22). As such, Vifor's construction reads: "hypochlorite being added in 1:1 molar ratio with respect to the aldehyde end group of the sugar." (Vifor Resp. Br. at 1).

At the *Markman* hearing, Biofer conceded that it would be willing to construe the disputed term "stoichiometric quantities" as "hypochlorite being added in an approximately 1:1 molar ratio with respect to the aldehyde end group of the sugar," with the caveat that in the specific case of the dextran, hypochlorite would be added in an approximately 2:1 molar ratio. (Markman Tr. at 98:4–25). Vifor, at the hearing, said it could not agree to Biofer's *Markman* construction and continued to argue that "the 1 to 1 [molar] ratio of the hypochlorite with respect to the aldehyde end groups is the plain and ordinary meaning" of "stoichiometric quantities." (*Id.* at 101:1–3). With Biofer's concession, the Court now decides whether the term means "approximately a 1:1 molar

particular stopping point." *Id.* Biofer is not seeking to add additional steps, only seeking to broaden the scope of the claim outside the claimed pH range.

ratio” or a “1:1 molar ratio,” and whether there should be a carve out for the specific dextran case.

To the first point, the Court construes the term to mean “hypochlorite being added in a 1:1 molar ratio with respect to the aldehyde end group of the sugar.” The specification provides two reactions which teach that hypochlorite is in a 1:1 molar ratio with the end aldehyde of the sugar during oxidation. (Decl. of Jeffrey D. Winkler in Supp. of Vifor’s Resp. Br. (“Winkler Decl.”), Dkt. No. 63-3 ¶ 78). These reactions in the specifications do not indicate that the hypochlorite should be added in an “approximately” 1:1 molar ratio. And, as with the precision of the pH range, if the inventors wanted to define this as an “approximately” 1:1 molar ratio, they could have done so. *Supra* at 5–6.

Having conceded that it would accept a 1:1 molar ratio (carving out an exception for dextran), Biofer’s attempt to then add the word “approximately” finds no support in the patent. As with the pH range, there is no language or intrinsic evidence supporting a modification of the term (in this case, the ratio, as opposed to the range). Indeed, Dr. Chirik, one of Biofer’s experts, relies on what a POSA would understand: “based on the specification as well as the knowledge in the art how to calculate a stoichiometric quantity of hypochlorite using the average [dextrose equivalent] value of the dextrin or dextran, which allows for a reasonable range of variation and imprecision in the calculation.” (Decl. of Paul J. Chirik, Ph.D. in Supp. of Pl. Biofer’s Op. Claim Construction Br. dated June 12, 2023, Dkt. No. 47 ¶ 31)).

The Court finds that Vifor’s construction is more in line with the patent language. First, the reactions in the patent’s specifications teach a 1:1 molar ratio. *See, e.g., Dow Chem. Co. v. Sumitomo Chem. Co., Ltd.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001) (“The

specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”). Further, the prosecution history supports Vifor’s construction: Dr. Marchi, in his declaration, described 0.9 moles of hypochlorite to 1 mole of end aldehyde as “under-stoichiometric.” (Marchi Decl. ¶ 7). Through the experiments, Dr. Marchi showed that stoichiometric quantity meant a 1:1 molar ratio, not a 0.9:1 molar ratio. (Winkler Decl. ¶ 80). Accordingly, the Court finds Biofer’s addition of the word “approximately” lacks support and adopts Vifor’s 1:1 molar ratio.

However, the Court also finds that the intrinsic evidence supports Biofer’s 2:1 dextran exception. The detailed description of the invention section of the ’320 Patent states, in the context of what is to be added to activate the sugar, “hypochlorite in aqueous solution in a stoichiometric quantity with respect to the aldehyde end groups present in the sugar, if not branched; *in the specific case of the dextran*, a hypochlorite quantity corresponding with the *double of the moles is used*.” (’320 Patent at col. 10, ll. 22–26) (emphasis added). Vifor’s response to Biofer’s 2:1 caveat was two-fold: it argued that the examples Biofer relied on do not reference stoichiometric amount, and that in the case of the dextran, “a 2 to 1 ratio cannot be approximately a 1:1 ratio.” (Markman Tr. at 111:5–16). First, the doubled molar ratio comes from the detailed description of the invention, not just Examples 6 and 7. And, as noted above, the line in the detailed description explicitly uses the term “stoichiometric quantity” within the same sentence, only three lines above. (’320 Patent at col. 10, ll. 22–26). As for Vifor’s contention that Biofer is trying to include a 2:1 ratio within the bounds of an approximately 1:1 ratio, the argument is without merit. In fact, the proposed construction expressly notes that the ratio for the dextran is a caveat, different from the “approximately 1:1 molar ratio.”

Accordingly, the Court construes the disputed term “said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups” as “hypochlorite being added in a 1:1 molar ratio with respect to the aldehyde end group of the sugar and added in a 2:1 molar ratio in the specific case of the dextran.”

CONCLUSION

Except for this *Markman* decision, this case is otherwise stayed pursuant to the parties’ agreement. (See Order dated Mar. 15, 2024, Dkt. No. 138).

SO ORDERED.

/s/ Sanket J. Bulsara March 29, 2024
SANKET J. BULSARA
United States Magistrate Judge

Brooklyn, New York